meeting. Submissions should be made by June 17, 1993, to Amanda B. Pedersen, FDA Chief Mediator and Ombudsman (address above).

Dated: May 11, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93-11708 Filed 5-17-93; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 76G-0189]

Market Basket; Withdrawal of GRAS Affirmation Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a petition (GRASP 6G0058) requesting that the agency affirm that chlorine spray containing 180 parts per million (ppm) of chlorine in water for use as a spray on beef carcasses is generally recognized as safe (GRAS).

FOR FURTHER INFORMATION CONTACT: Andrew D. Laumbach, Center for Food Safety and Applied Nutrition (HFS-217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-254-9519.

SUPPLEMENTARY INFORMATION: In the Federal Register of September 7, 1976 (41 FR 37658), FDA published a notice announcing that a petition (GRASP 6G0058) had been filed by Market Basket, 6014 South Eastern, Los Angeles, CA 90022. This petition asked that the agency affirm that chlorine spray containing 180 ppm of chlorine in water for use as a spray on beef carcasses is GRAS.

On October 30, 1981, FDA asked the firm for additional data to support the petition. The last correspondence from the petitioner was a letter dated February 11, 1982. This letter did not respond to the agency's request for additional information to affirm that the petitioned use of chlorine spray is GRAS. Moreover, the petitioner has submitted no further information or data to the agency.

On November 20, 1992, the agency sent a letter to the firm requesting the additional data and asking for a statement of the firm's intent with regard to the petition. FDA advised that if the requested information could not be submitted within 30 days of the date of the letter, then the petition should be withdrawn. Otherwise, the agency would proceed to publish a notice in the Federal Register to withdraw or deny the petition. The letter sent by special carrier could not be delivered to the petitioner's last known address: 13100 Molette St., Santa Fe Springs, CA 90670, and was returned to the agency. Therefore, the agency is announcing that it considers this petition to be withdrawn by the firm, without prejudice to a future filing, in accordance with 21 CFR 171.7(b).

Dated: May 7, 1993.

Douglas L. Archer,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 93-11642 Filed 5-17-93; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 93E-0147]

Determination of Regulatory Review Period for Purposes of Patent Extension; Lamisil Cream

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Lamisil Cream and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Karin L. Bolte, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Lamisil Cream. Lamisil Cream (terbinafine hydrochloride) is indicated for the topical treatment of the following dermatologic infections: interdigital tinea pedis (athlete's foot), tinea cruris (jock itch), or tinea corporis (ringworm) because of *Epidermophyton floccosum*, *Trichophyton mentagrophytes*, or *T. rubrum*. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Lamisil Cream (U.S. Patent No. 4,755,534) from Sandoz, Ltd., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. FDA, in a letter dated April 13, 1993, advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Lamisil Cream represented the first commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Lamisil Cream is 3,464 days. Of this time, 2,917 days occurred during the testing phase of the regulatory review period, while 547 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective:* July 9, 1983. The applicant claims June 6, 1983, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 9, 1983.

which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act*: July 3, 1991. The applicant claims June 30, 1991, as the date the new drug application (NDA) for Lamisil Cream (NDA 20–192) was initially submitted. However, FDA records indicate that NDA 20–192 was initially submitted on July 3, 1991.

3. *The date the application was approved*: December 30, 1992. FDA has verified the applicant's claim that NDA 20–192 was approved on December 30, 1992.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 543 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before July 19, 1993, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before November 15, 1993, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 10, 1993.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 93–11641 Filed 5–17–93; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 93N–0156]

Report on Voluntary Compliance by Food Retailers in Providing Nutrition Labeling Information for Raw Fruit and Vegetables and for Raw Fish; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a report entitled "Report on Voluntary Compliance by Food Retailers in Providing Nutrition Labeling Information for Raw Fruit and Vegetables and for Raw Fish." The report was prepared by the Division of Technical Evaluation, Office of Food Labeling, Center for Food Safety and Applied Nutrition, FDA.

DATES: The report is available on May 8, 1993. Comments may be received at any time.

ADDRESSES: Submit written comments and requests for single copies of the report to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. Comments and requests should be identified with the docket number found in brackets in the heading of this document. Send two self-addressed adhesive labels to assist that office in processing your requests. The report and received comments are available for public examination at Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Mary M. Bender, Center for Food Safety and Applied Nutrition (HFS–165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4466.

SUPPLEMENTARY INFORMATION: The Nutrition Labeling and Education Act of 1990 (the 1990 amendments) amended the Federal Food, Drug, and Cosmetic Act (the act) to require, among other things, that under section 403(q)(4) (21 U.S.C. 343 (q)(4)), FDA: (1) Identify the 20 most frequently consumed raw fruit, vegetables, and fish in the United States; (2) establish guidelines for the voluntary nutrition labeling of raw fruit and vegetables and of raw fish; and (3) issue regulations that define "substantial compliance" with respect to the adherence by food retailers to those guidelines. In the Federal Register of July 2, 1991 (56 FR 30458), FDA responded to those requirements by a proposal, and in the Federal Register of November 27, 1991 (56 FR 60880), the agency published a final rule on the nutrition labeling of raw fruit, vegetables, and fish (corrected on March 6, 1992 (57 FR 8174)).

FDA listed the 20 most frequently consumed raw fruit, vegetables, and fish in § 101.44 (21 CFR 101.44). In § 101.45 (21 CFR 101.45), FDA set forth guidelines on how these foods are to be nutrition labeled. Under these guidelines, nutrition labeling information may be provided within the retail departments where raw fruit and vegetables and raw fish are sold. Information may be made available in signs, posters, brochures, notebooks, or leaflets and may be supplemented by video, live demonstration, or other media.

In § 101.43 (21 CFR 101.43), FDA defined substantial compliance to mean that at least 60 percent of the food retailers sampled in a representative survey provide nutrition labeling information (as specified in the guidelines) for at least 90 percent of the foods that they sell that are included on the listing of the most frequently consumed raw fruit and vegetables and raw fish. FDA said that it would make separate determinations of substantial compliance for raw fruit and vegetables collectively and for raw fish (§ 101.43(a)). Section 403(q)(4)(C)(ii) of the act states that if substantial compliance is achieved by food retailers, FDA is to reassess voluntary labeling compliance every 2 years. If substantial compliance is not achieved, the act states that FDA is to propose to require that any person who offers raw fruit and vegetables or raw fish to consumers provide nutrition information for those foods (section 403(q)(4)(D)(i) of the act).

Based upon the results of a study conducted under contract, FDA concludes that substantial compliance by food retailers in providing nutrition labeling information for raw fruit and vegetables and for raw fish has been met when measured against criteria established in § 101.43. In actuality, the 60 percent compliance standard has been well exceeded. Aggregate percentages (i.e., percentages over all stores sampled) for both raw fruit and vegetables and for raw fish show that approximately three-fourths of the retail food stores surveyed by field representatives provide the voluntary nutrition labeling information.

Baseline data collected in 1991, prior to promulgation of the final rule on the nutrition labeling of raw fruit, vegetables, and fish showed that virtually no food retailers provided complete nutrition labeling information for raw fruit and vegetables or for raw fish. The dramatic increase from 1991 to